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09/989,342

11/20/2001

Robert C. Simpson

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05/17/2004

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EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

10

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/989,342

Applicant(s)

SIMPSON, ROBERT C.

Examiner

Catherine S. Williams

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12,15-18 and 51-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-12,15-18 and 51-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

The objections to claims 2 and 12 have been withdrawn in light of the Amendment dated 2/27/04.

Claim Rejections - 35 USC § 112

The rejection to claims 3-4 and 13-14 under 35 U.S.C. 112, second paragraph, has been withdrawn in light of the Amendment dated 2/27/04.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7, 10-16, 51-54 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Kuntz (US pat# 3,683,928). Kuntz discloses a catheter applicator. See figures 3-4. The device includes a sidewall (14) with a distal end piece (52), a proximal end piece (12), a loading aperture (28), a single inner cavity (between 14 and 52) and a dispensing aperture (50). The device is disclosed as being held within a user's hand and being made from semi-rigid material (thermoplastic). The sidewall has the shape of a cone, see figure (3-4). The catheter is loaded manually.

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Claims 1, 8, 10-11 and 15-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Gula et al (US Pat# 3,995,628). Gula discloses a catheter insertion device that includes a cylindrical sidewall (18) having a proximal and distal end (end with lip/flange; see figure 8). The distal end is connected to a distal end piece (16) that defines the upper border of a single inner cavity. As shown in figure 8, wall (28) has a gap connecting the annular area with the central area thereby maintaining one single cavity. The distal end piece includes a dispensing aperture (54) from where the catheter is extracted. See figures 7 and 8. The device is made from molded plastic. The loading of the catheter is performed manually. See figure 15-16.

Claims 1, 7, 10-11, 51-52 and 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Katerndahl et al (US Pat# 3,561,445). Katerndahl discloses a catheter placement unit that includes a conical sidewall (70) having a proximal and distal end (74). The distal end is connected to a distal end piece (72) that defines the upper border of a single inner cavity. The proximal end is connected to proximal end piece (78). The distal end piece includes a dispensing aperture from where the catheter is extracted. See figure 8.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 6 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz or Katerndahl. Kuntz or Katerndahl meet the claim limitations as described above but fails to include the dispenser being positioned with the distal end directed toward the user's thumb.

However, at the time of the invention, it would have been obvious to turn the dispenser in any orientation including having the distal end directed toward the user's thumb. The motivation for the alteration would have been in order to enhance the comfort of the device during use to the user or in order to enhance the usability of the device to facilitate the use of the device in hard to reach areas.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gula. Gula meets the claim limitations as described above but fails to include the dispenser being positioned with the distal end directed toward the user's thumb.

However, at the time of the invention, it would have been obvious to turn the dispenser in any orientation including having the distal end directed toward the user's thumb. The motivation for the alteration would have been in order to enhance the comfort of the device during use to the user or in order to enhance the usability of the device to facilitate the use of the device in hard to reach areas.

Claims 8-9 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz. Kuntz meets the claim limitations as described above but fails to include the shape of the sidewall as a cylinder or polyhedron.

At the time of the invention, it would have been obvious to change the shape of the sidewall. Further the Federal Circuit has held, where the only difference between the prior art

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and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. The motivation for changing the shape would have been in order to enhance the usability of the device.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gula. Gula meets the claim limitations as described above but fails to include the shape of the sidewall as a polyhedron.

At the time of the invention, it would have been obvious to change the shape of the sidewall. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. The motivation for changing the shape would have been in order to enhance the usability of the device.

Claims 9 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Katerndahl. Katerndahl meets the claim limitations as described above but fails to include the shape of the sidewall as a polyhedron.

At the time of the invention, it would have been obvious to change the shape of the sidewall. Further the Federal Circuit has held, where the only difference between the prior art and the claims was a recitation of relative dimension/size/proportion of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device. The motivation for changing the shape would have been in order to enhance the usability of the device.

Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuntz. Kuntz meets the claim limitations as described above but fails to include the loading the dispenser mechanically or by an automated process. However, Kuntz does teach that an objective of the device is to keep the catheter aseptic during insertion. Therefore, at the time of the invention, it would have been obvious to load the catheter either mechanically or by an automated process in order to eliminate human contact before use and thereby enhance the sterility of the device prior to use.

Response to Arguments

Applicant's arguments filed 2/27/04 have been fully considered but they are not persuasive.

Applicant argues that the Kuntz reference has more than one separate and distinct chamber, does not meet the limitation of a single inner cavity, and therefore, fails to anticipate. However, applicant is arguing that which is not claimed. The claim recites "at least one sidewall having a proximal end and a distal end, the distal end being connected to a distal end piece, thereby defining a single inner cavity." Basically, the claim language when interpreted in it's broadest form reads that the invention has a sidewall with two ends where one of the ends is connected to an end and that end in its connection to the sidewall form the boundaries of a single inner cavity. While the specification is used to understand the claim language, limitations from the specification and/or the drawings are not read into the claim language. While applicant is arguing that the Kuntz system does not have a single inner cavity, the claim language does not

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recite the system having a single inner cavity. Rather the claimed "walls" define a single inner cavity. The fact that the Kuntz reference may have additional chambers residing outside the confines of the claimed walls is irrelevant as long as the structures of the prior art that are being applied and used to read on the structures (i.e. walls) of the instant invention define only one, single inner cavity. Figure 2 most clearly shows the single inner cavity. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Limitations were removed from the independent claims in the Amendment dated 2/27/04 thereby broadening the scope of the independent claims. A new rejection, while making the action final, is therefore proper since the claims have been broadened. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this

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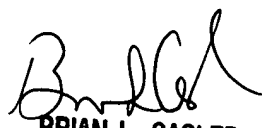
final action. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 703-308-4846.

The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 703-308-3552. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Catherine S. Williams *CSW*,
May 7, 2004


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